CLAIMS

What is claimed is:

Claim 1. A biopolymer marker comprising the sequence (R)HYGETKMNQRSSR(S) or an analyte thereof useful in indicating at least one particular disease state.

Claim 2. The biopolymer marker of claim 1 wherein said disease state is predictive of Alzheimers disease.

Claim 3. A method for evidencing and categorizing at least one disease state comprising:

obtaining a sample from a patient;

conducting mass spectrometric analysis on said sample;

evidencing and categorizing at least one biopolymer marker sequence or analyte thereof isolated from said sample; and,

comparing said at least one isolated biopolymer marker sequence or analyte thereof to the biopolymer marker sequence as set forth in claim 1;

wherein correlation of said isolated biopolymer marker and said biopolymer marker sequence as set forth in claim 1 evidences and categorizes said at least one

disease state.

Claim 4. The method of claim 3, wherein said step of evidencing and categorizing is particularly directed to biopolymer markers or analytes thereof linked to at least one risk of disease development of said patient.

Claim 5. The method of claim 3, wherein said step of evidencing and categorizing is particularly directed to biopolymer markers or analytes thereof related to the existence of a particular disease state.

Claim 6. The method of claim 3, wherein the sample is an unfractionated body fluid or a tissue sample.

Claim 7. The method of claim 3, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

Claim 8. The method of claim 3, wherein said mass spectrometric analysis is selected from the group consisting of Surface Enhanced Laser Desorption Ionization (SELDI) mass spectrometry (MS), Maldi Qq TOF, MS/MS,

TOF-TOF, and ESI-Q-TOF or an ION-TRAP.

Claim 9. The method of claim 3, wherein said patient is a human.

Claim 10. A diagnostic assay kit for determining the presence of the biopolymer marker or analyte thereof of claim 1 comprising:

at least one biochemical material which is capable of specifically binding with a biomolecule which includes at least said biopolymer marker or analyte thereof, and

means for determining binding between said biochemical material and said biomolecule;

whereby at least one analysis to determine a presence of a marker, analyte thereof, or a biochemical material specific thereto, is carried out on a sample.

Claim 11. The diagnostic assay kit of claim 10, wherein said biochemical material or biomolecule is immobilized on a solid support.

Claim 12. The diagnostic assay kit of claim 10 including:

at least one labeled biochemical material.

Claim 13. The diagnostic assay kit of claim 10, wherein said biochemical material is an antibody.

Claim 14. The diagnostic assay kit of claim 12, wherein said labeled biochemical material is an antibody.

Claim 15. The diagnostic assay kit of claim 10, wherein the sample is an unfractionated body fluid or a tissue sample.

Claim 16. The diagnostic assay kit of claim 10, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

Claim 17. The diagnostic assay kit of claim 10, wherein said biochemical material is at least one monoclonal antibody specific therefore.

Claim 18. A kit for diagnosing, determining risk-assessment, and identifying therapeutic avenues related to a disease state comprising:

at least one biochemical material which is capable of specifically binding with a biomolecule which includes at

least one biopolymer marker including the sequence (R)HYGETKMNQRSSR(S) or an analyte thereof related to said disease state; and

means for determining binding between said biochemical material and said biomolecule;

whereby at least one analysis to determine a presence of a marker, analyte thereof, or a biochemical material specific thereto, is carried out on a sample.

Claim 19. The kit of claim 18, wherein said biochemical material or biomolecule is immobilized on a solid support.

Claim 20. The kit of claim 18 including:

at least one labeled biochemical material.

Claim 21. The kit of claim 18, wherein said biochemical material is an antibody.

Claim 22. The kit of claim 20, wherein said labeled biochemical material is an antibody.

Claim 23. The kit of claim 18, wherein the sample is an unfractionated body fluid or a tissue sample.

Claim 24. The kit of claim 18, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

Claim 25. The kit of claim 18, wherein said biochemical material is at least one monoclonal antibody specific therefore.

Claim 26. The kit of claim 18, wherein said diagnosing, determining risk assessment, and identifying therapeutic avenues is carried out on a single sample.

Claim 27. The kit of claim 18, wherein said diagnosing, determining risk assessment, and identifying therapeutic avenues is carried out on multiple samples such that at least one analysis is carried out on a first sample and at least another analysis is carried out on a second sample.

Claim 28. The kit of claim 27, wherein said first and second samples are obtained at different time periods.

Claim 29. Polyclonal antibodies produced against a marker sequence ID including the sequence

(R)HYGETKMNQRSSR(S) or an analyte thereof in at least one animal host.

Claim 30. An antibody that specifically binds a biopolymer including a marker consisting of the sequence (R)HYGETKMNQRSSR(S) or at least one analyte thereof.

Claim 31. The antibody of claim 30 that is a monoclonal antibody.

Claim 32. The antibody of claim 30 that is a polyclonal antibody.

Claim 33. A process for identifying therapeutic avenues related to a disease state comprising:

conducting an analysis as provided by the kit of claim 18; and

interacting with a biopolymer consisting of the sequence (R)HYGETKMNQRSSR(S) or at least one analyte thereof;

whereby therapeutic avenues are developed.

Claim 34. The process for identifying therapeutic avenues related to a disease state in accordance with

claim 33, wherein said therapeutic avenues regulate the presence or absence of the biopolymer consisting of the sequence (R)HYGETKMNQRSSR(S) or at least one analyte thereof.

Claim 35. The process for identifying therapeutic avenues related to a disease state in accordance with claim 33, wherein said therapeutic avenues developed include at least one avenue selected from a group consisting of 1)utilization and recognition of said biopolymer markers, variants or moieties thereof as direct therapeutic modalities, either alone or in conjunction with an effective amount of a pharmaceutically effective carrier; 2)validation of therapeutic modalities or disease preventative agents as a function of biopolymer marker presence or concentration; 3)treatment or prevention of a disease state by formation of disease intervention modalities; 4)use of biopolymer markers or moieties thereof as a means of elucidating therapeutically viable agents, 5)instigation of a therapeutic immunological response; and 6) synthesis of molecular structures related to said biopolymer markers, moieties or variants thereof which are constructed and arranged to therapeutically intervene in said disease state.

Claim 36. The process for identifying therapeutic avenues related to a disease state in accordance with claim 35, wherein said treatment or prevention of a disease state by formation of disease intervention modalities is the formation of biopolymer/ligand conjugates which intervene at receptor sites to prevent, delay or reverse a disease process.

Claim 37. The process for identifying therapeutic avenues related to a disease state in accordance with claim 35, wherein said means of elucidating therapeutically viable agents includes use of a bacteriophage peptide display library or a bacteriophage antibody library.

Claim 38. A process for regulating a disease state by controlling the presence or absence of a biopolymer selected from the group consisting of the sequence (R)HYGETKMNQRSSR(S) or at least one analyte thereof.